

00025.013300

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
WALTER PRIKOSZOVICH) : Examiner: Edward J. Webman
Application No.: 10/054,490) : Group Art Unit: 1616
Filed: January 22, 2002) :
For: IMPROVEMENTS IN OR)
RELATING TO ORGANIC) :
COMPOUNDS)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION UNDER 37 C.F.R. § 1.132
OF MARTIN SCHNEIDER

Sir:

MARTIN SCHNEIDER declares and says that:

1. I have been employed by Sandoz AG and Novartis Pharma AG at its Basel, Switzerland, St. Johann facility for the past thirteen years. Most recently, I have occupied the position of Development Chemist and Process Manager.
2. I have received a bachelor degree in chemistry from the Basel Institute of Technology.
3. I have worked extensively with the purification of polylactide polymers with a central glucose moiety. I am familiar with the prosecution history of the present

application, including the most recent rejection of the pending claims under 35 U.S.C. §103(a) as obvious over Bodmer (U.S. Patent No. 5,538,739) in view of GB 2,145,422 and Reiners (U.S. Patent No. 4,879,402).

4. In my opinion, one of ordinary skill in the art would not combine the Bodmer, GB '422 and Reiners references. The chemistry involved in the Reiners reference is completely different from that of Bodmer and GB '422 and from that of the presently claimed invention. Reiners describes (methyl)acrylic acid derivatives containing urethane groups as monomeric components for dental materials. The monomers of Reiners are prepared by reacting a hydroxyalkyl(meth)acrylic acid ester with a diisocyanate in the presence of a catalyst (e.g., tin(II)octanoate) to form an isocyanatourethane, which is then reacted with a polyol; the monomers obtained thereby are used for the preparation of dental material by another polymerization reaction resulting in poly (meth)acrylates which are resistant to hydrolysis. By contrast, Bodmer and GB '422 describe the formation of polyester polymers. The polymers of Bodmer and GB '422 are prepared by a polymerization reaction of (cyclic) alphahydroxy carboxylic acids using polyhydroxy compounds (e.g., glucose) as the initiator and tin(II)octanoate as catalyst; the polylactide polymers obtained thereby are biodegradable, e.g., by hydrolysis.

5. What is more, Reiners generally operates in the field of dental polymers, which is wholly different from the field of both Bodmer and GB '422 and from the field of the present invention, namely, pharmaceutical formulation. For these reasons, it is my opinion that one of ordinary skill in this art would not look to a reference such as Reiners

when attempting to purify a pharmaceutical polymer such as disclosed in Bodmer and GB '422.

6. In my further opinion, even if Reiners were to be combined with Bodmer and GB '422, one of ordinary skill in the art would not arrive at the pharmaceutical composition of the present claims. Example 5 of Reiners is the only portion therein which mentions tin octanoate in combination with charcoal to obtain a colorless solution. However, there is no disclosure or suggestion in Reiners regarding what was present in the solution prior to charcoal treatment or what was present after treatment. It is equally unclear whether the solution of Reiners was colored prior to charcoal treatment or whether tin was removed by the method in the Reiners reference. In other words, Reiners does not teach removal of a tin octanoate catalyst from a polymer by activated charcoal treatment.

7. In addition, one of ordinary skill in the art would not arrive at the pharmaceutical formulation of the present invention which contains a polylactide polymer in a purified state by combining Reiners with Bodmer and GB '422. One of ordinary skill in the art would not recognize that activated charcoal will bind the octoate chain, removing the tin counterion as well. In fact, purification does not proceed in the manner proposed in the Office Action. In practice, the activated charcoal will remove the tin metal ion, but a second purification step is required to remove the ethyl hexanoate acidic group which remains after the tin metal ion removal. Hence, even if one of ordinary skill in the art were to combine Reiners with Bodmer and GB '422, at least the ethyl hexanoate impurity would remain in the polymer.

8. In conclusion, it is my opinion that one of ordinary skill in the art would not combine the Bodmer, GB '422 and Reiners references and, even if the references were combined, the result would not be the pharmaceutical formulation of the present invention which contains a polylactide polymer in a purified state.

I declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Subscribed this 2nd day of July, 2007.

M. Schneider
Martin Schneider